REMARKS

The present response is intended to be fully responsive to all points of objection and/or rejection raised by the Examiner and is believed to place the application in condition for allowance. Favorable reconsideration and allowance of the application is respectfully requested.

Applicants assert that the present invention is new, non-obvious and useful. Prompt consideration and allowance of the claims is respectfully requested.

Status of Claims

Claims **50-60** are pending in the application.

Claims **50-60** have been rejected.

CLAIM REJECTIONS

35 U.S.C. § 102 Rejection

In the Office action, the Examiner rejected claims 50-51 and 58-60 under 35 U.S.C. § 102(a) as anticipated by Schulman et al (U.S. Patent No. 6,088,608). Applicants traverse the rejection for at least the reasons that follow.

With respect to independent claim 50, according to the Examiner, Schulman et al disclose a system for measuring physiological parameters in the body of a patient, "such as gastroesophageal reflux," the system comprising:

A monitoring device 10, said monitoring device comprising a housing adapted to be implanted in the body of a patient by attachment to tissue inside the body and a plurality of sensors 10a-c etc. included in said housing, best seen in Figure 5 (Col. 3:32-46), wherein each of the plurality of sensors is capable of independently measuring a different respective physiological parameter ***indicative of gastroesophageal reflux***, i.e., pH (Col. 4:64; Col. 5:1-4) and wherein said monitoring device periodically transmits a signal indicative of the value

of the respective physiological parameter measured by each of the plurality of sensors (Col. 5:16-23);

A receiver 16 that receives signals from the monitoring device, said signals representing measurements made by the respective plurality of sensors, monitors the physiological parameters ***indicative of gastroesophageal reflux*** based on said plurality of signals, for example, by analysis of the pH values by the physician.

(Office Action at pp. 2-3, ¶ 5; emphasis added)

The cited portions of Schulman et al are provided below:

> In a preferred configuration, a plurality of sensors, e.g., ***three sensors, are daisy-chained together and implanted within a patient in the same general area***, i.e., in the same tissue or body fluids. Each sensor operates independently of the others. ***If all the sensors are functioning properly, then the output data obtained from each sensor should be approximately the same. The data sensed by each sensor may thus be used as a cross-check against the data sensed by the other sensors.*** In a similar manner, the information obtained from the periodic integrity tests may be regularly compared and checked with the corresponding integrity test information obtained from the other sensors of the same group of chained-together sensors. In this manner, the overall integrity of the integrity tests is itself checked periodically (Col. 3:32-46; emphasis added)
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> * * *
>
> The sensors 10 may comprise any type of implantable sensor, e.g., a temperature sensor, an oxygen sensor, a CO.sub.2 sensor, a glucose sensor, a pH sensor, a salinity sensor, or the like. Each sensor 10 typically includes at least one electrode 14 adapted to interact with or sense some prescribed substance that may be present within (or absent from) the tissue 12 to varying degrees. To this end, each sensor 10 operates independently of the other sensors being used, yet each is implanted within the same general area of the tissue or fluids 12. (Col. 4:62-Col. 5:4)
>
> * * *
>
> The sensors 10 are connected to a sensor controller 16 by way of a suitable coupling cable 18. The controller 16 may or may not be implantable. If the controller 16 is not implanted, then appropriate means are employed, as is known in the art, along the length of the cable 18 to transcutaneously interface with implanted sensors 10 so

> that appropriate signal communication may take place between the implanted sensors 10 and the controller 16. A common transcutaneous interface technique known in the art is inductive coupling, using both implanted and external coils. Alternatively, optical, magnetic, or other types of signal transmission could be used to achieve a transcutaneous signal link through the cable 18. (Col. 5:15-27)

Schulman et al are directed to implantable sensors and more particularly to integrity tests performed on a regular basis to confirm proper operation. (Col. 1:5-9)

Although Schulman et al disclose a plurality of sensors, Schulman et al do not disclose that the plurality of sensors is included in a "housing adapted to be implanted in the body of a patient by attachment to tissue," as required by claim 50.

Further, Schulman et al do not disclose that each of the plurality of sensors "is independently capable of measuring a ***different*** respective physiological parameter ***indicative of gastroesophageal reflux***," as also required by claim 50. There is nothing in Schulman et al discussing gastroesophageal reflux. More importantly, Schulman et al disclose that the plurality of sensors exists as part of the integrity testing, that is, ***each of the plurality of sensors in Schulman et al monitors the same physiological parameter***. See above, Col. 3:32-46 and also:

> Various types and kinds of integrity tests may be performed in connection with the sensors 10 in accordance with the present invention. One basic integrity test that may be made involves monitoring the sensor output signal, i.e., that signal which provides a measure of whatever it is that the sensor is measuring, from each of a plurality of sensors located within the same general tissue area, to see if there is a consensus between such measurements. ***That is, assume there are five identical sensors all implanted within the same general tissue area, and all configured to measure the same substance within that tissue area. If all five sensors provide approximately the same measurement data, e.g., within about 20% of each other, then that indicates--i.e., provides integrity test data--that all five sensors are performing properly. Should four of the sensors agree, and one disagree, then that indicates the disagreeing sensor is likely malfunctioning***. As a result of such finding, all sensor data subsequently obtained from such malfunctioning sensor may be ignored, or alternatively the sensor may be disabled. (Col. 5:56-Col. 6:7; emphasis added)

Still further, there is nothing in Schulman et al disclosing a receiver that "monitors the physiological parameters indicative of gastroesophageal reflux" and "determines at least the presence of gastroesophageal reflux," as required by claim 50.

A claim is invalid as anticipated under 35 U.S.C. § 102(a) if:

> the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for patent. . .

35 U.S.C. § 102(a) (pertinent part). It is settled that a patent claim is invalid as anticipated if, within

> the four corners of a single, prior art document . . . every element of the claimed invention [is described], either expressly or inherently, such that a person of ordinary skill in the art could practice the invention without undue experimentation.

Callaway Golf Co. v. Acushnet Co., 576 F.3d 1331, 1346; 91 U.S.P.Q.2D (BNA) 1705 (Fed. Cir. 2009) (citation and quotation omitted) Accordingly, because Schulman et al do not describe every element of independent claim 50, that claim cannot be invalid as anticipated under § 102(a) by Schulman et al.

It is further settled that if an independent claim is not anticipated by prior art, then its dependent claims, which necessarily include the limitations of the independent claim, are not anticipated either. See, e.g., *Trintec Indus., Inc. v. Top-U.S.A.. Corp.*, 295 F.3d 1292, 1296; 63 U.S.P.Q.2D (BNA) 1597 (Fed. Cir. 2002); *RCA Corp. v. Applied Digital Data Sys., Inc.*, 730 F.2d 1440, 1446; 221 U.S.P.Q. (BNA) 385 (Fed. Cir. 1984). Accordingly, because independent claim 50 is not anticipated by Schulman et al., Schulman et al. anticipate one or more of dependent claims 51, 58-60.

Still further, additional issues bases exist for traversing the Examiner's rejection of dependent claims 58-60. With respect to dependent claim 58, the Examiner argues that Schulman et al disclose the receiver 16 is capable of monitoring a change in pH as a function of distance/location. (Office Action at p. 3, ¶ 7) However, there is nothing in Schulman disclosing this. Indeed, the sole mention of pH in Schulman et al is at Col. 4:64, where they disclose that the sensor may comprise a pH sensor. There is no disclosure in Schulman et al that change in pH can be monitored as a function of distance/location.

With respect to dependent claim 59, the Examiner argues that Schulman et al:

> disclose said plurality of sensors 10 include a pH monitor and an auxiliary sensor, wherein said auxiliary sensor is capable of measuring an auxiliary physiological parameter that is not a pH parameter, wherein the receiver is configured to receive a pH reading from said pH sensor and to adjust said pH reading based on the measured value of the physiological parameter (Col. 3:32-46)

(Office Action at pp. 3-4, ¶ 8) Schulman et al.'s disclosure at Col. 3:32-46 is shown above. As shown, Schulman et al ***do not*** disclose that the plurality of sensors includes "an auxiliary sensor…to measure an auxiliary physiological parameter that is not a pH parameter," as required by claim 59. Rather, Schulman et al disclose that the plurality of sensors exists as part of the integrity testing, that is, ***each of the plurality of sensors in Schulman et al monitors the same physiological parameter***.

With respect to claim 60, the Examiner argues that Schulman et al disclose the auxiliary physiological parameter is selected from the group consisting of: an ion concentration, a temperature, and a pressure (Col. 4:59-67). (Office Action at p. 4, ¶ 9) However, as Schulman et al do not disclose measurement of an auxiliary physiological parameter, this rejection respectfully is moot.

Accordingly, for the foregoing reasons, the Examiner's rejection of claims 50-51 and 58-60 under 35 U.S.C. § 102(a) as anticipated by Schulman et al. is respectfully traversed.

35 U.S.C. § 103 Rejection

In the Office action, the Examiner rejected dependent claims 52-55 under 35 U.S.C. § 103(a) as obvious over Schulman et al in view of Brune (U.S. Patent No. 5,984,875). Applicants traverse the rejection for at least the reasons that follow.

With respect to dependent claim 52, the Examiner argues that:

> Schulman et al disclose the plurality of sensors includes a pH monitor (Col.4:64) but do not explicitly disclose said sensors include an RF transmitter and a microprocessor. Brune teaches the use of an R,F transmitter 9, 10 to transmit the signals from an analogous implanted sensor 2 (Col.6:40-42). Brune also teaches analogous implanted sensor 2 includes a microprocessor 7 that periodically receives a signal

> from the sensor and induces the RF transmitter to periodically send an RF signal indicative of the sensor (Col. 6:22-42).

(Office Action at pp. 4-5, ¶ 12)

The disclosure (or lack thereof) of Schulman et al. has been discussed. As noted, inter alia, there is nothing disclosed in Schulman et al. concerning monitoring of pH. The cited portions of Brune are reproduced below:

> Controller 7 activates and receives signals from the temperature sensor 8, controls transmitter 9 which transmits data burst via antenna 10, and controls timing/power management circuit 11. Controller 7 is externally programmed by inductive programming 12. For example, the controller 7 can be inductively programmed to set an identification code, ***the cycle period for data bursts***, a calibration factor for the temperature sensor, etc.
>
> The ingestible bolus is powered by a battery 13 and ***includes a timing/power management circuit 11 which conserves battery life by maintaining the bolus in a "sleeping" mode until data bursts cycles are triggered. The timing/power management circuit 11 turns the system power on, causing controller 7 to activate temperature sensor 8 and obtain therefrom a temperature signal***. The controller 7 then encodes the temperature signal and an identification code with an error detection and correction algorithm and feeds encoded data signal to transmitter 9 which transmits the encoded data signal as a data burst via antenna 10. (Col. 6:22-42; emphasis added)

Brune discloses a system and apparatus for monitoring the core temperature of ***ruminant animals***. The system includes an ***ingestible*** bolus which, when swallowed by a ruminant animal, senses and transmits information, including the core temperature of the ruminant animal. The system includes a receiver which receives the information transmitted from the ingestible boluses. The bolus has a suitable size and density which ensure that it is not regurgitated from the animal's rumen or reticulum. The bolus is capable of remaining in the animal's rumen or reticulum throughout the life of the animal. (Col. 4:29-39) The ***ingestible*** bolus includes a sensor for sensing physiological parameters, such as temperature. Other physiological parameters can be sensed by incorporating sensors such as electrical pH sensors, and similar sensors that can be used monitor other chemical components that are susceptible to redox reactions, pressure sensors, and the like. (Col. 5:20-28)

There is no disclosure in Brune concerning an ***implantable*** monitoring device, nor is there any disclosure that the system of Brune is suitable for humans, and particularly for measuring/monitoring/detecting physiological parameters indicative of gastroesophageal reflux, as claimed in the present claims.

Further, the Examiner provides no credible motivation to combine Schulman et al with Brune to arrive at the invention of claim 52. According to the Examiner,

> Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Schulman et al so that the plurality of sensors includes an RF monitor as an effective means to transmit the signal information wirelessly. Also, it would have been obvious to one of ordinary skill in the art at the time of the invention was made to modify the plurality of sensors of Schulman et al as modified by Brune to include a microprocessor that periodically receives a signal from the pH monitor and induces the monitor as an effective means to periodically transmit the pH information signal.

(Office Action at p. 5, ¶ 12)

As noted, Schulman et al do not disclose the invention of claim 50, or of claim 51 (from which claim 52 depends). The Examiner points to nothing in Brune that cures the deficiencies of Schulman et al.

Further, the Examiner makes no showing evidencing the level of ordinary skill in the art at the time of the claimed invention. The Examiner provides no evidence of what the level of ordinary skill in the art was, or what knowledge was within the level of such person, or why such a person or ordinary skill would have possessed this knowledge. However, under *KSR International Co. v. Teleflex Inc.*, 550 U.S. 398; 82 U.S.P.Q.2D 1385 (2007), such an analysis must be made explicit:

> [T]he claimed subject matter may involve more than the simple substitution of one known element for another or the mere application of a known technique to a piece of prior art ready for the improvement. Often, it will be necessary for a court to look to interrelated teachings of multiple patents; the effects of demands known to the design community or present in the marketplace; ***and the background knowledge possessed by a person having ordinary skill in the art, all in order to determine whether there was an apparent reason to combine the known elements in the fashion claimed by the***

> ***patent at issue. To facilitate review, this analysis should be made explicit***.

KSR, 550 U.S. at 417-18 (citing *In re Kahn*, 441 F.3d 977, 988; 78 U.S.P.Q.2D 1329 (Fed. Cir. 2006)) (emphasis added)

The Examiner's argument is a conclusory attempt to justify an improper rejection under 35 U.S.C. § 103(a). This is improper. As the Federal Circuit said in *In re Kahn*:

> [R]ejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.

441 F.3d at 988 (citations omitted).

With respect to dependent claims 53-54, the Examiner's rejection, citing Brune, fails to address or cure the deficiencies in Schulman et al. (Office Action at p. 5, ¶ 13) As for the Examiner's statement that

> it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Schulman et al as modified by Brune such that during the first interval the RF transmission is disabled and during the second interval the pH monitor is disabled, wherein the disabling occurs when the respective function is not performed…as an effective way to enhance the battery life conservation by only enabling the proper function as it is being used and disabling it during all other times

(Office Action at pp. 5-6, ¶ 14), as with the rejection of claim 52, the Examiner makes no showing of the level of ordinary skill in the art and offers no motivation to combine Schulman et al with Brune to arrive at the claimed invention. Again, nothing in Brune cures the deficiencies in Schulman et al. with respect to independent claim 50.

Likewise, with respect to dependent claim 55, the Examiner's rejection, citing Brune, fails to address or cure the deficiencies in Schulman et al. (Office Action at p. 6, ¶ 15). Further, the Examiner makes no showing of the level of ordinary skill in the art and offers no motivation to combine Schulman et al with Brune to arrive at the claimed invention. Again, nothing in Brune cures the deficiencies in Schulman et al. with respect to independent claim 50.

Accordingly, for the foregoing reasons, the Examiner's rejection of claims 52-55 under 35 U.S.C. § 103(a) as obvious over Schulman et al in view of Brune (U.S. Patent No. 5,984,875) respectfully is traversed.

The Examiner also rejected dependent claims 56-57 under 35 U.S.C. § 103(a) as obvious over Schulman et al. in view of Brune in further view of U.S. Patent No. 6,416,471 (Kumar et al.). Applicants traverse the rejection for at least the reasons that follow.

According to the Examiner:

> Schulman et al in combination with Brune disclose the receiver above but do not disclose the receiver worn by the patient or include [ ] circuitry to sense the position of the patient. Kumar et al disclose an analogous receiver 20 work by the patient best seen in Figure 1 as well as circuitry to sense a position of the patient (Col. 11:35-41). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the receiver of Schulman et al as modified by Brune to be worn by the patient and also include circuitry to sense a position of the patient as taught by Kumar et al for ease of transportation and to improve the invention by also providing valuable information pertaining to the position of the patient respectively, wherein it is then also obvious to one within the art for the receiver to also periodically record the position of the patient for the purpose of record.

(Office Action at pp. 6-7, ¶ 17) The cited portion of Kumar et al. is reproduced below:

> The signal transfer unit 20 may also have an ***internal position sensor*** which, when the patient is carrying signal transfer unit 20, ***indicates when the patient is in the horizontal position and will switch when the patient's position changes towards the vertical by more than 15 degrees***. A three axis sensor or accelerometer may be used for this function. The signal transfer unit 20 may also have the facility for the connection of a microphone for recording lung or breathing sounds. (Col.11:35-43; emphasis added)

Kumar et al. are directed to a system and method for monitoring vital signs and capturing data from a patient remotely using radiotelemetry techniques. In particular, the present invention is a low cost, patient-friendly, ambulatory monitoring system for remote electronic capture of ***non-invasive*** vital signs data including, e.g., full waveform ECG, respiration rate, skin temperature, and blood pressure. (Col. 1:6-19)

The portable remote patient telemonitoring system has four separate elements, each with different functions within the system: (i) an adhesive, cordless, disposable sensor band with electrode patches, other sensors, and transmission circuitry for the detection and transmission of vital signs data, the sensor band being positioned on the patient by the patient; (ii) a small signal transfer unit that can either be worn by the patient or positioned nearby, e.g., on a desk or chair or at the bedside., the signal transfer unit receiving data from the sensor band and forwarding it to a base station; (iii) a base station that receives data transmissions from the signal transfer unit and is designed to connect to conventional phone lines for transferring the collected data to a remote monitoring station; and (iv) a remote monitoring station, allowing the presentation and review of data (including event flags) forwarded by the sensor band and other sensors (Col. 4:39-5:19; see also Col. 7:61-8:2).

There is no disclosure in Kumar et al concerning an ***implantable*** monitoring device, nor is there any disclosure that the system of Kumar is suitable for measuring/monitoring/detecting pH or other physiological parameters indicative of gastroesophageal reflux, as claimed in the present claims.

Further, as with Brune (above), the Examiner's rejection here, citing Kumar et al., fails to address or cure the deficiencies in Schulman et al. (Office Action at pp. 6-7, ¶ 17) Still further, the Examiner makes no showing of the level of ordinary skill in the art and offers no motivation to combine Schulman et al with Brune and further with Kumar et al. to arrive at the claimed invention. Again, nothing in Brune or Kumar et al. cures the deficiencies in Schulman et al. with respect to independent claim 50.

Accordingly, for the foregoing reasons, the Examiner's rejection of claims 56-57 under 35 U.S.C. § 103(a) as obvious over Schulman et al. in view of Brune in further view of U.S. Patent No. 6,416,471 (Kumar et al.) respectfully is traversed.

Conclusion

In view of the foregoing remarks, the pending claims 50-60 are deemed to be allowable. Their favorable reconsideration and allowance is respectfully requested.

Should the Examiner have any question or comment as to the form, content or entry of this Response to Office Action, the Examiner is requested to contact the undersigned at the telephone number below. Similarly, if there are any further issues yet to be resolved to advance the prosecution of this application to issue, the Examiner is requested to telephone the undersigned counsel.

Please charge any fees associated with this paper to Deposit Account No. 50-3355.

Respectfully submitted,

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